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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,985	12/21/2001	Jay M. Short	DIVER1370-8	9024

25225 7590 06/12/2007
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EXAMINER	
RAMIREZ, DELIA M	
ART UNIT	PAPER NUMBER
1652	
MAIL DATE	DELIVERY MODE
06/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/034,985	SHORT, JAY M.	
	Examiner	Art Unit	
	Delia M. Ramirez	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/5/2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-28,30,31,33-41,44,46,48-59,64 and 66-72* is/are pending in the application.

4a) Of the above claim(s) *15-18,59,69 and 70* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-11,13,19,23-28,30,31,33-40,50-53,56,57,64,67,68,71 and 72* is/are rejected.

7)☒ Claim(s) *12,14,20-22,41,44,46,48,49,54,55,58 and 66* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/5/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Claims 8-28, 30-31, 33-41, 44, 46, 48-59, 64, 66-72 are pending.

Applicant's amendment of claims 8, 12-20, 24, 49-51, 53-59, 66-72 as submitted in a communication filed on 4/5/2007 is acknowledged.

As indicated in the Final action of 1/11/2006 and the Non Final action of 10/12/2006, this application contains claims 15-18, 59, 69-70 drawn to an invention non-elected without traverse in a communication filed on 2/24/2005. Claims 8-14, 19-28, 30-31, 33-41, 44, 46, 48-58, 64, 66-68, 71-72 are at issue and are being examined herein.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 4/5/2007 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Specification

2. The specification remains objected to due to the presence of hyperlinks on page 28, line 2. While the Examiner has been able to locate a previous amendment of the specification deleting hyperlinks on pages 25-26, there are no amendments of the specification where the hyperlink of page 28 has been deleted. Appropriate correction is required.

Terminal Disclaimer

3. The terminal disclaimer filed on 4/5/2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6110719 and any patent granted on Application Number 10/601319, 10/933115, and 11/056354 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Objections

4. Claims 12, 50, 56 are objected to due to the recitation of "polypeptide-encoding nucleic acid" and "polypeptide-expressing nucleic acid". The use of this language is confusing since this language has not being used in the claims from which claims 12, 50, 56 depend. For clarity and consistency, it is suggested that the terms be amended to simply recite "nucleic acid" since it is clear from the claims which nucleic acid is being referred to. Appropriate correction is required.

5. Claim 54 is objected to due to the recitation of "signal peptide (a leader sequence) and has a sequence of". For consistency, it is suggested the term be amended to recite "signal peptide (a leader sequence) and has the sequence of". See, for example, claims 55, 58, 66. Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 67-68, 71-72 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claims 67-68 and 71-72 are indefinite in the recitation of "(a) lacking a homologous (native) signal peptide, (b)....(c)....or (d) comprising the amino acid sequence of (a), (b), or (c) encoded by a polynucleotide..... SEQ ID NO: 1 lacking the bases encoding amino acid residues 1-22..." for the following reasons. First, the term "lacking the bases encoding amino acid residues 1-22" is indefinite absence a reference sequence for those amino acids (i.e., lacking the bases encoding amino acid residues 1-22 of SEQ ID NO: X). For examination purposes, it will be assumed that the term reads "lacking the bases encoding amino acid residues 1-22 of SEQ ID NO: 2". In addition, it is noted that while item (d) requires that the amino acid sequence lacks a signal peptide (as required by items (a), (b) and (c)), the specification discloses that amino acids 1-22 of SEQ ID NO: 2 correspond to a signal peptide. Thus, the limitation in item (d) requiring lack of a homologous signal peptide and also lack of amino acids 1-22 of SEQ ID NO: 2 is unclear and confusing since one cannot determine whether amino acids 1-22 represent only a fragment of the signal peptide, or if the limitations as recited are merely redundant. For examination purposes, no patentable weight will be given to the term "comprising the amino acid sequence of (a), (b), or (c)" in item (d). Also, it is noted that the term in item (d) reciting "wherein the polypeptide having a phytase activity has the amino acid sequence of SEQ ID NO: 2...." as used in item (d) is confusing. This section of item (d) will be interpreted as being item (e) and it will be interpreted as reciting "(e) comprising SEQ ID NO: 2 lacking amino acid residues 1 to 22 of SEQ ID NO: 2, or comprising SEQ ID NO: 2 from amino acids 23 to 432". Correction is required.

Claim Rejections - 35 USC § 112, First Paragraph

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claims 8-11, 19, 23-28, 30-31, 33-41, 46, 48, 50-53, 56-57, 64, 67, 71-72 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description and enablement

requirements. In view of Applicant's amendment and assertion that the intended genus of *E. coli* phytases does not encompass any phytase found in a recombinant *E. coli* cell, these rejections are hereby withdrawn.

Claim Rejections - 35 USC § 103

11. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

12. Claims 8-11, 13, 19, 23-28, 30-31, 33-40, 50-53, 56-57, 64, 67-68, 71-72 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al. (U.S. Patent No. 5939303 filed on 11/6/1996, issued 8/17/1999; cited in the IDS) in view of Greiner et al. (Archives of Biochemistry and Biophysics 303(1):107-113, 1993; cited in the IDS). This rejection has been discussed at length in the Final action mailed on 1/11/2006 and the Non Final action mailed on 10/12/2006. It is maintained for the reasons of record and those set forth below.

13. Applicant argues that neither Greiner nor Cheng teach or suggest the use of *E. coli* phytase in a feed or food composition. Applicant also refers to the declaration previously submitted by Dr. Nelson Barton on 7/11/2006 and reiterated the arguments previously presented in the response of 7/11/2006. Applicant submits that the claims are not directed to known *E. coli* phytases but a food/feed composition comprising an *E. coli* phytase, which Applicant indicates as novel. Applicant points out that recognition of a property of one component in a multi-component composition is not sufficient for the Office to disregard an expert declaration setting forth secondary evidence of non-obviousness that includes copying, commercial success and long-felt need. Applicant also refers to the teachings of Warden et al. and Wodzinski et al. in support of the argument that before the present invention, preparing a composition comprising an *E. coli* phytase would have been technically difficult to achieve. Applicant also refers to the teachings of Golovan et al. in support of the argument that even after the priority date of the present

application, the public state of the art was still searching for an appropriate phytase for use in foods and feeds.

14. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the instant rejection. For the record, it is noted that while Applicant asserts in the response of 4/5/2007 that the references by Warden et al. and Wodzinski et al. were provided in an IDS, there is no record of these references in the file and no IDS has been filed citing these references. Thus, these references have not been considered by the Examiner. Any reference to Warden et al. and Wodzinski et al. by the Examiner will be made based solely on what has been indicated by Applicant in the response as a relevant teaching.

With regard to the teachings of Cheng and Greiner, it is reiterated herein that none of this references alone teach the claimed invention. Instead, it is the combination of both references along with the knowledge of one of ordinary skill in the art which renders the claimed invention obvious for the reasons extensively discussed in previous actions. Also, it is noted that while it is agreed that Greiner et al. do not specifically teach using the *E. coli* phytase in a food/feed composition, the fact that Greiner et al. provide a statement indicating why phytases are of interest for the reduction of phytate in food and feedstuff and how supplementation of animal feedstuff with phytases increases the availability of phosphate (page 107) is a clear indication to one of skill in the art that Greiner et al. contemplates the use of the *E. coli* phytase in a food/feed composition. If this is not the case, it is unclear as to why Greiner et al. would have stated that phytases are of interest for increasing the nutritional value of foods/feeds.

The Barton declaration and arguments related to this declaration have been previously addressed. While Applicant asserts that the Office should not disregard the Barton declaration based solely on a well-known property of the *E. coli* phytase (high activity at acidic conditions) and should considered other components in a composition as claimed, it is noted that neither the specification nor the claims refer to additional components in the phytase composition that would give such composition novel characteristics/properties not present if such composition were to comprise only an *E. coli* phytase. The

teachings of the specification clearly indicate that it is the enzymatic activity of the *E. coli* phytase (hydrolysis of phytate) which is the desired feature in the feed/food compositions claimed because a food/feed composition which comprises such enzyme would have additional nutritional value by virtue of the extra phosphate released from phytate-containing foods. Thus, contrary to Applicant's assertion, the Examiner is not disregarding other compounds in a multi-component composition. Instead, the Examiner is addressing the only component which is described by Applicant's specification as the key component in the compositions claimed.

With regard to the teachings of Warden et al. and Wodzinski et al. as cited by Applicant, it is noted that based on the teachings referred to by Applicant in the response of 4/5/2007 (the Examiner does not have copies of these references), none of these references teach that producing the *E. coli* phytase or a feed/food composition comprising said phytase is not possible. Even if it is assumed that producing the *E. coli* phytase of Greiner et al. would have been difficult at the time the invention was made, this is irrelevant since (1) production of small amounts of the *E. coli* phytase of Greiner et al. still would have been possible, and (2) the prior art provided clear motivation to prepare a food/feed composition comprising the *E. coli* phytase of Greiner et al. Thus, one of skill in the art could have made a food/feed composition comprising an *E. coli* phytase. While difficulties in the production of the *E. coli* phytase at an industrial scale would have explained why producing a feed/food composition comprising said phytase was not economically viable at the time the invention was made, these alleged difficulties still would have not stopped one of skill in the art to make the claimed composition since Greiner et al. teach how to make the required phytase, why phytases are used in feed/food compositions, and the properties of the *E. coli* phytase which make it desirable in a composition as claimed were well known at the time the invention was made. Also, it is noted that none of these references teach away from using an *E. coli* phytase in a food/feed composition as claimed. Wodzinski et al. (according to Applicant) state the difficulties in producing large amounts of a phytase from *A. niger* and do not in any way teach or suggest

the impossibility of producing an *E. coli* phytase to use in a food/feed composition. Warden et al. suggest (according to Applicant) that their food/feed composition most likely comprised an *E. coli* enzyme which made available additional amounts of phosphate to poultry. If this is the case, the crude *E. coli* whole cell lysates of Warden et al. would have comprised a phytase. It is also noted that while Wodzinski et al. (according to Applicant) refers to the many years it took to make phytase a commercial product, they refer to the year 1962, which is almost 40 years prior to the priority date of the instant application, at a time when recombinant production of proteins was unknown. The state of the art in 1962 was certainly not the state of the art at the time the invention was made. Interestingly , the teachings of Warden et al., as indicated by Applicant, further provide motivation for one of skill in the art to use an *E. coli* phytase in food/feed composition, since this reference (according to Applicant) teaches that feeding crude *E. coli* whole cell lysates to poultry was beneficial and clearly suggests that a phytase in the lysates could have provided additional phosphate.

With regard to the argument that the teachings of Golovan et al. show that even after the priority date of the present application, the public state of the art was still searching for an appropriate phytase for use in foods and feeds, this is irrelevant since the teachings of Golovan et al. do not in any way teach away from using an *E. coli* phytase in a food/feed composition nor do they teach the impossibility of producing an *E. coli* phytase.

Therefore, for the reasons of record and those set forth above, the composition of Greiner and Cheng render the claimed invention obvious to one of ordinary skill in the art.

Double Patenting

15. Claims 8-14, 19-20, 23, 26-31, 33-41, 44, 46, 50-55, 64, 66, 67-68, 71 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-7 of U.S. Patent No. 6110719.

16. Claims 21-22, 24-25, 48-49, 56-58, 72 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-7 of U.S. Patent No. 6110719 in view of Cheng et al. (U.S. Patent No. 5939303 filed on 11/6/1996, issued 8/17/1999; cited in the IDS).

17. Claims 8-14, 19-20, 23, 24, 26-31, 33-41, 44, 46, 48-49, 50-58, 64, 66, 67-68, 71-72 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 10/933115.

18. Claims 8-14, 19-20, 23, 26-31, 33-41, 44, 46, 50-55, 64, 66, 67-68, 71 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 88, 96, 103 of copending Application No. 11/056354.

19. Claims 21-22, 24-25, 48-49, 56-58, 72 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 88, 96, 103 of copending Application No. 11/056354 in view of Cheng et al. (U.S. Patent No. 5939303 filed on 11/6/1996, issued 8/17/1999; cited in the IDS).

20. In view of Applicant's terminal disclaimer filed on 4/5/2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6110719 and any patent granted on Application Number 10/601319, 10/933115, and 11/056354, these rejections are hereby withdrawn.

Allowable Subject Matter

21. Claims 12, 14, 20-22, 41, 44, 46, 48-49, 54-55, 58, 66 appear to be allowable over the prior art of record but are objected to as being dependent upon a rejected base claim and/or the reasons set forth above under Claim Objections.

Conclusion

22. No claim is in condition for allowance.

23. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

24. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Delia M. Ramirez, Ph.D.
Primary Patent Examiner
Art Unit 1652

DR
June 6, 2007